

OFE 403

Patent Attorney's Docket No. <u>1032469-000007</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Sam T. LINDHOLM et al.) Group Art Unit: 1647
Application No.: 10/759,244) Examiner: D. Romeo
Filed: January 20, 2004) Confirmation No.: 7086
For: OSTEOGENIC DEVICE AND A METHOD FOR PREPARING THE DEVICE)))

COMMUNICATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants would like to thank Examiner Romeo for the telephone conference with Applicant's representative of December 18, 2006 regarding the following. In the Notice of Allowance issued October 3, 2006 (copy attached), the Examiner attached a Form PTO-1449, originally filed with an Information Disclosure Statement in the present application on August 2, 2004. The Examiner indicated that certain references cited in the Information Disclosure Statement failed to fully comply with 37 CFR 1.98(a)(s), which requires a legible copy of each cited foreign patent document and each non-patent literature publication.

Applicants assert that the references cited in the Information Disclosure Statement filed on August 2, 2004 in the present application fully comply with 37 CFR 1.98(a)(s), as they were cited and placed in the record in parent application Serial No. 09/125,963 on September 26, 2003. A full, complete copy of the

Application No. 10/759,244 Attorney's Docket No. <u>1032469-000007</u>

Page 2

Information Disclosure Statement filed in the parent application on September 26,

2003 is attached, along with a copy of the stamped postcard showing receipt by the

U.S. Patent and Trademark Office. Applicants also submit herewith copies of the

cited references for the Examiner's convenience as he requested.

Per the telephone call with the Examiner of December 18, 2006, Applicant

request that the Examiner acknowledge he has considered the attached references

on behalf of the present application.

Applicants believe that a fee is not required for this submission, however, in

the event a fee is necessary the Commissioner is hereby authorized to charge

Deposit Account No. <u>02-4800</u>, such fee.

Respectfully submitted,

Date: December 19, 2006

By:

Deborah H.

Registration/No. 45,904

P.O. Box 1404

Alexandria, Virginia 22313-1404

(703) 836-6620

DEC 19 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re Patent Application of

LINDHOLM et al.

Group Art Unit: 1647

Application No.: 09/125,963

Examiner: David S. Romeo

Filed: November 24, 1998

Confirmation No.: 8371

For:

OSTEOGENIC DEVICE AND A

METHOD FOR PREPARING THE

DEVICE

INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

[X] No additional fee for submission of an IDS is required.

By:

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 26, 2003

Deborah H. Yellin

Registration No. 45,904

P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620

9-26-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DEC 19 200

In re Patent Application of

LINDHOLM et al.

Application No.: 09/125,963

Filed: November 24, 1998

For: OSTEOGENIC DEVICE AND A

METHOD FOR PREPARING THE

DEVICE

Group Art Unit: 1647

Examiner: David S. Romeo

Confirmation No.: 8371

FOURTH INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, LINDHOLM et al. hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b) no fee or statement is required.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 26, 2003

Deborah H. Yellin Registration No. 45,904

P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620

9-26-03

(05/03)

200	A	SHEET I OF 4
Substitute for forms 1449A/PTO & 1449B/PTO	ATTORNEY'S DKT No. 032469-001	APPLICATION NO. 09/125,963
EQUIDMIT THEODY (1 mron) Bross of the	APPLICANT	
FOURTH INFORMATION DISCLOSURE	Sam T. LINDHOLM et al	·
STATEMENT BY APPLICANT	FILING DATE	GROUP
4	November 24 1998	1647

DEC 1 9 2006

FOURTH INFORMATION DISCLOSURE			Sam T. LINDHOLM et al.						
	STATEMENT BY APPLICANT FILING DATE November 24, 19			FILING DATE November 24, 1998	GROUP 1647				
200	2006 1047								
200	Zi)			I C DATENT DO	O 1104 C 0.17 O				
	<i>5</i> /	· · · · · · · · · · · · · · · · · · ·	<u> </u>	J.S. PATENT DO	DCUMENTS		leeuo	/Public	ation
7	Examiner Initials	Document Number	Kind Code (if known)	Na	ame of Patentee or Applican of Cited Document	t		Date	
		4,975,527	, , , , , , , , , , , , , , , , , , , ,	KOEZUKA et al				-DD-YY -04-19	
			FOI	REIGN PATENT	DOCUMENTS				
	Examiner Initials	Document Number	Kind Code (if known)		Country	Date of Publica (MM-DD-YYY		Trans Yes	lation No
		WO 94/26322			PCT	11-24-199		162	140
		WO 95/24474			PCT	09-14-199	5		
-		WO 95/33830			PCT	12-14-199	5		
<u> </u>	·	Т			URE DOCUMENTS				
	Examiner Initials	item (book	, magazine, jourr	nal, serial, symposiun publisher, city and/o	RS), title of the article (when n, catalog, etc.), date, page(or country where published.	s), volume-issue n	umber(
		SURGERY (1995), pp.	312-318, vol. 33	nentally created defect, Churchill Livingston	cts: a review," BRITISH JOURN ie, Edinburgh, Scotland.				
		BODEN, S.D. et al., " Lippincott Williams &	Video-Assisted L	ateral Intertransverse	Process Arthrodesis," SPIN	E (1996), pp. 2689	-2697,	vol. 21	1
	BOSTROM, M., et al., "Use of Bone Morphogenetic Protein-2 in the Rabbit Ulnar Nonunion Model," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1996), pp. 272-282, no. 327, Lippincott Williams & Wilkins, Philadelphia, PA.								
		CLEMENT, J.H., et al	., "Bone morphog	genetic protein 2 in th	ne early development of Xen	opus laevis," MECI	HANISMS	S OF	
		DEVELOPMENT (1995), COOK, S.D., et al., "F	Recombinant Hun	nan Bone Morphoger	etic Protein-7 Induces Heali	ing in a Canine Lo	ng-Bon	e Sean	nental
L	COOK, S.D., et al., "Recombinant Human Bone Morphogenetic Protein-7 Induces Healing in a Canine Long-Bone Segmental Defect Model," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1994), pp. 302-312, no. 301, J.B. Lippincott, Philadelphia, PA.								
		THE JOURNAL OF BONE	E AND JOINT SURG	ERY, (1994), pp. 827	teogenic Protein-1 on Healin -838, vol. 76-A, Amer. Vol.,	Boston, MA.			
L		Substitute for Spinal F	usions," SPINE (1994), pp. 1655-1663	man Osteogenic Protein (rh0 , vol. 19, Lippincott Williams	& Wilkins, Hagers	stown, i	MD.	
		COOK, S.D., et al., "E Primates," BOSTON .	ffect of Recombi	nant Human Osteoge AND JOINT SURGERY	enic Protein-1 on Healing of , (1995), pp. 734-750, Amer	Segmental Defect ican ed. 77(5), Bo	s in Noi	n-Huma A.	
		COOK, S.D., et al., "C Lippincott, Philadelphi	osteogenic Protei a, PA.	n-1," CLINICAL ORTHO	PAEDICS AND RELATED RESE	ARCH (1996), pp. 2	9-38, n	o. 324,	
		DUDLEY, A.T., et al., eye," GENES & DEVELO	"A requirement for present (1995). b	or bone morphogene p. 2795-2807, vol. 9	tic protein-7 during developm Cold Spring Harbor Laborat	nent of the mamm	alian ki	dney a	nd VY
		EHRNBERG, A., et al Procedure in Large Di	., "Comparison o aphyseal Defects	f Demineralized Allog s in Sheep." THE Jou	geneic Bone Matrix Grafting	(the Urist Procedu	re) and	the His	zarov
	Orthopaedic Research Society, American Ed. Journal of Bone and Joint Surgery, Boston, MA. EINHORN, T.A., et al., "The Healing of Segmental Bone Defects Induced by Demineralized Bone Matrix," THE JOURNAL OF BONE AND JOINT SURGERY (1984), pp. 274-279, vol. 66-A, The Journal of Bone and Joint Surgery, Boston, MA.								
	FANG, J., et al., "Stimulation of new bone formation by direct transfer of osteogenic plasmid genes," PROC. NATL. ACAD. SCI. (1996), pp. 5753-5758, vol.93 (USA), National Academy of Sciences, Washington, DC.								
	FISCHGRUND, J.S., et al., "Augmentation of Autograft Using rhBMP-2 and Different Carrier Media in the Canine Spinal Fusion Model", JOURNAL OF SPINAL DISORDERS (1996), pp. 467-472, vol. 10, No. 6, Lippincott Williams & Wilkins, Hagerstown, MD.								
	GAO, T.J., et al., "Microscopic evaluation of bone-implant contact between hydroxyapatite, bioactive glass and tricalcium phosphate implanted in sheep diaphyseal defects," BIOMATERIALS (1995), pp. 1175-1179, vol. 16, Oxford, England.								
	GAO, T.J., et al., "Enhanced Healing of Segmental Tibial Defects in Sheep by a Composite Bone Substitute Comprised of Tricalcium Phosphate Cylinder, Bone Morphogenetic Protein and Type IV Collagen, JOURNAL OF BIOMEDICAL MATERIALS RESEARCH (1996), vol. 32, Interscience, Wiley, Hoboken, NJ.						of		
		sheep: mechanics and	immune assay,	" INTERNATIONAL C	e morphogenetic protein rep DRTHOPAEDICS,, German	Ceramics Society.	Cologr	ne. Ger	many.
L		Segmental Diaphysea	Defect in Sheep	o," BIOCERAMICS, pp.	al Coral and Tricalcium Phos 199-204, vol. 8, German Ce	eramics Society, C	oloane.	g a Germa	any.
		GAO, T.J., et al., "Cor	nposite of Bone I	Morphogenetic Protei	n (BMP) and Type IV Collag NATIONAL ORTHOPAEDICS (AC	en Coral-Derived	Coral		
							-		-

Substitute for forms 1449A/PTO & 1449B/PTO	ATTORNEY'S DKT NO. 032469-001	APPLICATION NO. 09/125,963
FOURTH INFORMATION DISCLOSURE	APPLICANT Sam T. LINDHOLM et al.	
STATEMENT BY APPLICANT	FILING DATE November 24, 1998	GROUP 1647

	NON PATENT LITERATURE DOCUMENTS
Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	GAO, T.J., et al., "Bone Inductive Potential and Dose-Dependent Response of Bovine Bone Morphogenetic Protein Combir with Type IV Collagen Carrier," ANNALES CHIRURGIAE ET GYNAECOLOGIAE (1993), pp. 77-84, vol. 207, University of Tampere Finland, University of Helsinki, Finland.
	GERHART, T.N., et al., "Healing Segmental Femoral Defects in Sheep Using Recombinant Human Bone Morphogenetic Protein," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1993), pp. 317-326, no. 293, J.B. Lippincott Company, Philadelphia, PA.
	HECKMAN, J.D., et al., "The Use of Bone Morphogenetic Protein in the Treatment of Non-Union in a Canine Model," THE JOURNAL OF BONE AND JOINT SURGERY (1991), pp. 750-764, vol. 73-A, The Journal of Bone and Joint Surgery, American Volume, Boston, MA.
	HELM, G.A., et al., "Utilization of type I collagen gel, demineralized bone matrix, and bone morphogenetic protein-2 to enhance autologous one lumbar spinal fusion," J. NEUROSURGERY. (1997), pp. 93-100, vol. 86, Charlottesville, VA.
	HOGAN, B.L.M., "Bone morphogenetic proteins: multifunctional regulators of vertebrate development," GENES & DEVELOPMENT (1996), pp. 1580-1594, vol. 10, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY.
	HOLLIGER, E.H., et al., "Morphology of the Lumbar Intertransverse Process Fusion Mass in the Rabbit Model: A Comparis Between Two Bone Graft Materials — rhBMP-2 and Autograft," JOURNAL OF SPINAL DISORDERS (1996), pp. 125-128, vol. 9, Lippincott Williams & Wilkins, Hagerstown, MD.
	HOLLINGER, J. & LEONG, K., "Poly(α-hydroxy acids): carriers for bone morphogenetic proteins," BIOMATERIALS (1996), pp 187-194, vol. 17, Elsevier Science Limited, Butterworth-Heinemann, Oxford, England.
	HOTZ, G. & HARR, G., "Bone substitute with osteoinductive biomaterials – current and future clinical applications," INT. J. ORAL MAXILLOFAC. SURG. (1994), pp. 413-417, vol. 23, Munksgaard, Copenhagen, Denmark
	HU, Y.Y., "Experimental studies on reconstituted xenograft and its clinical application," Chinese Journal of Surgery, Vol. 31, no. 12, pp. 709-713, Zhonghua yi xue hui, Wai ke xue hui, Beijing, China.
	JOHNSON, E.E. & URIST, M.R., "Distal Metaphyseal Tibial Nonunions Associated with Significant Bowing Deformity and Cortical Bone Loss: Treatment with Human Bone Morphogenetic Protein (h-BMP) and Internal Fixation," (1989), pp. 613-62 vol. 63, Nippon Seikeigeka Gakkai Zasshi, Japan.
	JOHNSON, E.E., et al., "Repair of Segmental Defects of the Tibia with Cancellous Bone Grafts Augmented with Human Bo Morphogenetic Protein," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 249-257, no. 236, JB Lippincott, Philadelphia, PA.
	JOHNSON, E.E., et al., "Bone Morphogenetic Protein Augmentation Grafting of Resistant Femoral Nonunions," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 257-265, no. 230, JB Lippincott, Philadelphia, PA.
	JOHNSON, E.E., et al., "Autogeneic Cancellous Bone Grafts in Extensive Segmental Ulnar Defects in Dogs," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1989), pp. 254-265, no. 243, JB Lippincott, Philadelphia, PA.
	KATO, F., "Experimental study of chemical spinal fusion in the rabbit by means of bone morphogenetic protein," (1990), PubMed 2380596, Nippon Seikeigeka Gakkai Zasshi, Japan.
	KUBOKI, Y., et al., "Two Distinctive BMP-Carriers Induce Zonal Chondrogenesis and Membranous Ossification, Respective Geometrical Factors of Matrices for Cell-Differentiation," CONNECTIVE TISSUE RESEARCH (1995), pp. 219-226, vol. 32, Taylor Francis, Philadelphia, PA.
	LEE, S.C., et al., "Healing of large segmental defects in rat femurs is aided by RhBMP-2 in PLGA matrix," JOURNAL OF BIOMEDICAL MATERIALS RESEARCH (1994), pp. 1149-1156, vol. 28, Wiley Interscience, Hoboken, NJ.
	LINDE, A. and HEDNER, E., "Recombinant Bone Morphogenetic Protein-2 Enhances Bone Healing, Guided by Osteopromotive e-PTFE Membranes: An Experimental Study in Rats," CALCIFIED TISSUE INT. (1995), pp. 549-553, vol. 56, Springer-Verlag, NY.
	LINDHOLM, T.S., et al., "Response of Bone Marrow Stroma Cells to Demineralized Cortical Bone Matrix in Experimental Spinal Fusion in Rabbits," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 296-302, no. 230, JB Lippincott, Philadelphia, PA.
	LINDHOLM, T.C., et al., "Bone Morphogenetic Proteins Regenerating Skull and Maxillo-Mandibular Defects," BONE MORPHOGENETIC PROTEINS (1996), pp. 149-155, R.G. Landes Company, Austin, TX.
	LINDHOLM, T.S. and GAO, T.J., "Functional Carriers for Bone Morphogenetic Proteins," ANNALES CHIRURGIAE ET GYNAECOLOGIAE Supplementum, (1993), pp. 3-12, vol. 82, University of Helsinki, Helsinki, Finland.
	LOVELL, T.P., et al., "Augmentation of Spinal Fusion With Bone Morphogenetic Protein in Dogs," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1989), pp. 266-274, no. 243, JB Lippincott, Philadelphia, PA.
	MIYAMOTO, S. & TAKAOKA, K., "Bone Induction and Bone Repair by Composites of Bone Morphogenetic Protein and Biodegradable Synthetic Polymers," Annales Chirurgiae et Gynaecologiae Supplement. 69-76, vol. 82, University of Helsinki, Helsinki, Finland.
	MUSCHLER, G.F., et al., "Evaluation of Human Bone Morphogenetic Protein 2 in a Canine Spinal Fusion Model," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1994), pp. 229-240, no. 308, J.B. Lippincott Company, Philadelphia, PA.
	NILSSON, O.S., et al., "Bone Repair Induced by Bone Morphogenetic Protein in Ulnar Defects in Dogs," THE JOURNAL OF BONE AND JOINT SURGERY, British Volume, (1986), pp. 635-642, vol. 68-B, London, UK.

		511EE1 <u>5</u> Or 4
Substitute for forms 1449A/PTO & 1449B/PTO	ATTORNEÝ'S DKT NO. 032469-001	APPLICATION NO. 09/125,963
FOURTH INFORMATION DISCLOSURE	APPLICANT Sam T. LINDHOLM et al.	
STATEMENT BY APPLICANT	FILING DATE November 24 1998	GROUP

	NON PATENT LITERATURE DOCUMENTS
Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	ODA, S., et al., "Ectopic bone induction in recombinant human bone morphogenetic protein-2 (rhBMP-2) combined with biphasic calcium phosphate (BCP)," (1996), The Journal of Stomatological Society, Japan
	ONO, I., et al., "Promotion of the Osteogenetic Activity of Recombinant Human Bone Morphogenetic Protein by Prostaglan E,," BONE (1996), pp. 581-588, vol. 19, Elsevier Science Inc., NY.
	PANGANIBAN, G.E.F., et al., "Biochemical Characterization of the <i>Drosophila dpp</i> Protein, a Member of the Transforming Growth Factor β Family of Growth Factors," MOLECULAR AND CELLULAR BIOLOGY (1990), pp. 2669-2677, vol. 10, American Society for Microbiology, Washington, DC.
	PETIT, J.C. & RIPAMONTI, U., "Tissue Segregation Enhances Calvarial Osteogenesis in Adult Primates," THE JOURNAL OF CRANIOFACIAL SURGERY (1994), pp. 34-43, vol. 5, Little, Brown & Co., Boston, MA.
	RAGNI, P. & LINDHOLM T.S., "Interaction of Allogeneic Demineralized Bone Matrix and Porous Hydroxyapatite Biocerami in Lumbar Interbody Fusion in Rabbits," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1991), pp. 292-299, no. 272, JB Lippincott, Philadelphia, PA.
	RAGNI, P., et al., "Spinal Fusion Induced by Porous Hydroxyapatite Blocks (HA)," pp. 133-144, Italian Journal of Orthopaedics & Traumatology, Bologna, Italy.
	RAGNI, P.C. & LINDHOLM, T.S., "Bone Formation and Static Changes in the Thoracic Spine at Uni- or Bilateral Experiment Spondylodesis with Demineralized Bone Matrix (DBM)," pp. 237-252, Italian Journal of Orthopaedics & Traumatology, Bologna, Italy.
	RILEY, E.H., et al., "Bone Morphogenetic Protein-2," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1996), pp. 39-46, no 324, JB Lippincott, Philadelphia, PA.
	SAILER, H.F. & KOLB, E., "Application of purified bone morphogenetic protein (BMP) preparations in cranio-maxillo-facial surgery," JOURNAL OF CRANIO-MAXILLO-FACIAL SURGERY (1994), pp. 191-199, vol. 22, Churchill Livingstone, Edinburgh, Scotland.
	SAILER, H.F. & KOLB, E., "Application of purified bone morphogenetic protein (BMP) in cranio-maxillo-facial surgery," JOURNAL OF CRANIO-MAXILLO-FACIAL SURGERY (1994), pp. 2-11, vol. 22, Churchill Livingstone, Edinburgh, Scotland.
	SAMPATH, T.K. & REDDI, A.H., "Homology of bone-inductive proteins from human, monkey, bovine, and rat extracellular matrix," PROC. NATL. ACAD. SCI. USA (1983), pp. 6591-6595, vol. 80, National Academy of Sciences, Washington, DC.
	SAMPATH, T.K., et al., "Drosophila transforming growth factor β superfamily proteins induce endochondral bone formation mammals," PROC. NATL. ACAD. SCI. USA (1993), pp. 6004-6008, vol. 90, National Academy of Sciences, Washington, DC.
	SANDHU, H.S., et al., "Evaluation of rhBMP-2 With an OPLA Carrier in a Canine Posterolateral (Transverse Process) Spin Fusion Model," SPINE (1995), pp. 2669-2683, vol. 20, Lippincott-Raven Publishers
	SANDHU, H.S., et al., "Effective Doses of Recombinant Human Bone Morphogenetic Protein-2 in Experimental Spinal Fusion," SPINE (1996), pp. 2115-2122, vol. 21, Lippincott Williams & Wilkins, Hagerstown, MD.
	SCHIMANDLE, J.H., et al., "Experimental Spinal Fusion With Recombinant Human Bone Morphogenetic Protein-2," SPINE (1995), pp. 1326-1337, vol. 20, Lippincott Williams & Wilkins, Hagerstown, MD.
	SHEEHAN, J.P., et al., "Molecular Methods of Enhancing Lumbar Spine Fusion," NEUROSURGERY (1996), pp. 548-554, vol.
	STAEHLING-HAMPTON, K., et al., "Specificity of Bone Morphogenetic Protein-related Factors: Cell Fate and Gene Expression Changes in <i>Drosophila</i> Embryos Induced by decapentaplegic but not 60A," CELL GROWTH & DIFFERENTIATION (1994), pp. 585-593, vol. 5, American Association for Cancer Research, Philadelphia, PA.
	SUN, Y., et al., "Repair of large cranial defect using allogeneic cranial bone and bone morphogenetic protein," Pubmed 7600438 (1995), Chinese Journal of Plastic Surgery and Burns, Beiling, China.
	TORIUMI, D.M., et al., "Mandibular Reconstruction With a Recombinant Bone-Inducing Factor," ARCH OTOLARYNGOL HEAD NECK SURG (1991), pp. 1101-1112, vol. 117, American Medical Association, Chicago, IL.
	URIST, M.R., et al., "Regeneration of an enchondroma defect under the influence of an implant of human bone morphogenetic protein," THE JOURNAL OF HAND SURGERY (1986), pp. 417-419, Vol. 11A, Churchill Livingstone, Secaucus, N
	VAN EEDEN, S.P. & RIPAMONTI, U., "Bone Differentiation in Porous Hydroxyapatite in Baboons Is Regulated by the Geometry of the Substratum: Implications for Reconstructive Craniofacial Surgery," PLASTIC AND RECONSTRUCTIVE SURGER' (1994), pp. 959-966, vol. 93, Lippincott Williams & Wilkins, Hagerstown, MD.
	VILJANEN, V.V., et al., "Partial Purification and Characterization of Bone Morphogenetic Protein from Bone Matrix of the Premature Moose (Alces alces): Degradation of Bone-Inducing Activity during Storage," (1996), pp. 447-460, vol. 28, European Surgical Research, Karger, Basel, Switzerland.
	VILJANEN, V.V., "Allogeneic and xenogeneic bone morphogenetic protein in skeletal reconstruction," (Academic Dissertation UNIVERSITY OF TAMPERE (1997), Tampere, Finland
	WHARTON, K.A., et al., "Drosophila 60A gene, another transforming growth factor β family member, is closely related to human bone morphogenetic proteins," PROC. NATL. ACAD. Sci. USA (1991), pp.9214-9218, vol. 88, National Academy of Sciences, Washington, DC.
	WOLFE M.W. & COOK, S.D., "Use of osteoinductive implants in the treatment of bone defects," MEDICAL PROGRESS THROL TECHNOLOGY (1994), pp. 155-168, vol. 20, Kluwer Academic, Boston, MA.

SHEET 4 OF 4

		SILEET <u>4</u> Or <u>4</u>
Substitute for forms 1449A/PTO & 1449B/PTO	ATTORNEY'S DKT NO. 032469-001	APPLICATION NO. 09/125,963
FOURTH INFORMATION DISCLOSURE	APPLICANT Sam T. LINDHOLM et al.	
STATEMENT BY APPLICANT	FILING DATE	GROUP
	November 24, 1998	1647

	NON PATENT LITERATURE DOCUMENTS
Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	YASKO, A.W., et al., "The Healing of Segmental Bone Defects, Induced by Recombinant Human Bone Morphogenetic Protein (rhBMP-2)," THE JOURNAL OF BONE AND JOINT SURGERY, (1992), pp. 639-670, vol. 74-A, American Ed. Journal of Bone and Joint Surgery, Boston, MA.

Claratura	Examiner	Date
		Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

INFORMATION DISC STATEMENT BY APP

Complete if Known **Application Number** 10/759,244 Filing Date January 20, 2004 **First Named Inventor** Sam T. Lindholm et al. **Examiner Name Attorney Docket Number** 032469-007

(use as many sheets as necessary)

5

DEC 1,9 2006

U.S.	PATENT	DOCUMENTS

Examiner Examinates	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
DR	4,294,753		URIST	10-13-1981
	4,434,094		SEYEDIN et al.	02-28-1984
	4,455,256		URIST	06-19-1984
	4,563,350		NATHAN et al.	01-07-1986
	4,608,199		CAPLAN et al.	08-26-1986
	4,627,982		SEYEDIN et al.	12-09-1986
	4,681,763		NATHANSON et al.	07-21-1987
	4,737,578		EVANS et al.	04-12-1988
	4,761,471		URIST	08-02-1988
	4,774,228		SEYEDIN et al.	09-27-1988
	4,774,322		SEYEDIN et al.	09-27-1988
	4,789,732		URIST	12-06-1988
	4,798,885		MASON et al.	01-17-1989
	4,804,744		SEN	02-14-1989
	4,810,691		SEYEDIN et al.	03-07-1989
	4,843,063		SEYEDIN et al.	06-27-1989
	4,886,747		DERYNCK et al.	12-12-1989
	4,968,590		KUBERASAMPATH et al.	11-06-1990
	4,975,527		KOEZUKA et al.	12-04-1990
	5,011,691		OPPERMANN et al.	04-30-1991
	5,106,626		PARSONS et al.	04-21-1992
	5,108,753		KUBERASAMPATH et al.	04-28-1992
	5,187,076		WOZNEY et al.	02-16-1993
	5,393,739		BENTZ et al.	02-10-1995
	5,849,880		WOZNEY et al.	12-15-1998
	5,631,142		WANG et al.	05-20-1997
	6,190,880		ISRAEL et al.	02-20-2001
	6,207,813		WOZNEY et al.	03-27-2001
V	6,245,889		WANG et al.	06-12-2001

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Document Number	Kind Code (if known)	Carain	Date of Publication	Translation	
	140.00.000		DOT	(MM-DD-YYYY)	Yes	No
	WO 00/00205		PCT	01-14-1088		
	WO 00/00707		PCT	10 10 1009		
	140 0000000		DOT		<u> </u>	
	WO 00/00700		101	10-19-1909	T	l
	WO 90/09799		POT	04-19-1990		
-	WO 91/02744		700	20.07.1004	 	
	770 51702144		207	03-01-1331		
	VVO 9 1700002		PCT	03-02-1991		
	WO 91/10047		POT	44.00.4004		
DR	WO 94/26322		PCT	11-24-1994		
	WOOFMARA		DCT		ļ	
				00-14-1995		i
	VVO 95/33830		PCT	12-14-1995		
DR	41 30 546		DE	03-18-1993		

Examiner Date	
Cianatura	
STABILITY Considered Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

· Substitute for form 14	HBA/PTO & 1	449B/P1	ro	Complete if Known		
		FIRS	ST .	Application Number	10/759,244	
INFO	RMATI	ON I	DISCLOSURE	Filing Date	January 20, 2004	
STAT	EMEN.	T B\	APPLICANT	First Named Inventor	Sam T. Lindholm et al.	
	(use as man	y sheets	as necessary)	Examiner Name		
Sheet	2	of	5	Attorney Docket Number	032469-007	

	NON-PATENT LITERATURE DOCUMENTS
xaminer Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. AAROE, M., et al., "Healing of experimentally created defects: a review." RECTISH JOURNAL OF ORAL & MAXILLOFACIAL SURGERY (1995), pp. 312-318, vol. 33, Churchill Livingstone, Edinburgh, Scotland.
DR	AONO, AKI, et al., "Potent Ectopic Bone-Inducing Activity of Bone Morphogenetic Protein-4/7 Heterodimer," Biochemical and Biophysical Research Communication (1995), pp. 670-677, Academic Press, Inc.
	BODEN, S.D. et al., "Video-Assisted Lateral Intertransverse Process Arthrodesis." SPINE (1996), op. 2689-2697, vol. 21. Lippincott Williams & Wilkins, Hagerslown, MD.
	BOSTROM, M., et al., *Use of Bone Morphogenetic Protein-2 in the Rabbit Ulnar Nonunion Model,* CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1996), pp. 272-282, no. 327, Lippincott Williams & Wilkins, Philadelphia, PA.
	CLEMENT, J.H., et al., "Bone morphogenetic protein 2 in the early development of Xenopus laevis," MECHANISMS OF DEVELOPMENT (1995), pp. 357-370, vol. 52, Elsevier Science, Limenck, Ireland.
	COOK, S.D., of al. "Recombined Human Rose Mombingenatic Protein," Induces Healing in a Capine Long Rose Segmental Defeat
	Model, CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1994), pp. 302-312, no. 301, J.B. Lippincott, Philadelphia, PA. COOK, S.D., et al., *The Effect of Recombinant Human Osteogenic Protein-1 on Healing of Large Segmental Bone Defects.* THE JOURNAL OF BONE AND JOINT SURGERY, (1994), pp. 827-838, vol. 76-A, Amer. Vol., Boston, MA.
	COOK S.D. et al. *In Vivo Evaluation of Recombinant Human Osteopenic Protein (rhOP-1) Implants As a Bone Graft Substitute for Spinal Fusions,* SPINE (1994), pp. 1655-1663, vol. 19, Lippincott Williams & Wilkins, Hagerstown, MD.
	COOK. S.D., et al., "Effect of Recombinant Human Osteogenic Protein-1 on Healing of Segmental Defects in Non-Human Primates," BOSTON JOURNAL OF BONE AND JOINT SURGERY, (1995), pp. 734-750, American ed. 77(5), Boston, MA.
	COOK, S.D., et al., *Osteogenic Protein-1.* CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1998), pp. 29-38, pp. 324, IR Lippincott, Philadelphia, PA.
DR	DAMIEN et al., "A Composite of Natural Coral, Collagen, Bone Protein and Basic Fibroblast Growth Factor Tested in a Rat Subcutaneous Model", Annales Chirugiae et Gynaecologiae, Supplementum, (1993) 207, 117-28.
DR	DART et al., Transforming growth factors from a human tumor cell: characterization of transforming growth factor beta and identification of high molecular weight transforming growth factor alpha. Biochemistry, (1985 Oct 8) 24 (21) 5925-31.
	DUDLEY, A.T., et al., "A requirement for bone morphogenetic protein-7 during development of the mammalian kidney and eye," GENES & DEVELOPMENT (1995), pp. 2/95-2807, Vol. 9, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY.
	EHRNBERG, A., et al., "Comparison of Demineralized Allogeneic Bone Matrix Grafting (the Urist Procedure) and the Ilizarov Procedure in Large Giaphysoal Sofods in Choop," The Journal of Bone Avid Joint Sungent, (1993), pp. 438-447, vol. 11,
·	Orthopaedic Research Society, American Ed. Journal of Bone and Joint Surgery, Boston, MA. EINHORN, T.A., et al., "The Healing of Segmental Bone Defects Induced by Demineralized Bone Matrix." THE JOURNAL OF BONE AND
	JOINT SURGERY (1984), pp. 274-279, vol. 66-A, The Journal of Bone and Joint Surgery, Boston, MA. FANG. 1. et al. "Stimulation of new bone formation by direct transfer of estangenic plasmid genes." Spoc. Natl. Acad. Sci. (1995).
	pp. 5753-5758, vol.93 (USA), National Academy of Sciences, Washington, DC.
	FISCHGRUND, J.S., et al., "Augmentation of Autografi Using mBMP-2 and Different Carrier Media in the Canine Spinal Fusion Moder, JOURNAL OF SPINAL DISORDERS (1990), pp. 407-472, vol. 10, No. 6, Uppincon vulliams & Wilkins, Hagerstown, MD.
DR	GAO, T.J., et al., "Microscopic evaluation of bone-implant contact between hydroxyapatite, bloactive glass and tricalcium phosphate implanted in sheep diaphyseal defects," BIOMATERIALS (1995), pp. 1175-1179, vol. 16, Oxford, England.
	GAO, T.J., et al., "Enhanced Healing of Segmental Tiblal Defects in Sheep by a Composite Bone Substitute Comprised of Tricalcium Phosphate Cylinder, Bone Morphogenetic Protein and Type IV Collagen, JOURNAL OF BIOMEDICAL MATERIALS RESEARCH (1996), vol. 32, Interscience, Wiley, Hoboken, NJ.
	GAO, T.J., et al., "A coral composite implant containing bone morphogenetic protein repairs a segmental tibial defect in sheep: mechanics and immune assay," INTERNATIONAL ORTHOPAEDICS,, German Ceramics Society, Cologne, Germany.
	GAO, T.J., et al., "Comparative Study on Potential of Natural Coral and Tricalcium Phosphate Cylinders in Healing a Segmental Diaphyseal Defect in Sheep," BIOCERAMICS, pp. 199-204, vol. 8, German Ceramics Society, Cologne, Germany.
	GAO, T.J., et al., "Composite of Bone Morphogenetic Protein (BMP) and Type IV Collagen, Coral-Derived Coral Hydrozyapatite and Tricalcium Phosphate Ceramics," INTERNATIONAL ORTHOPAEDICS (ACCEPTED), Springer Verlag, Berlin, Germany.
	GAO, T.J., et el., "Bone Inductive Potential and Dose-Dependent Response of Bovine Bone Morphogenetic Protein Combined with Type IV Collagen Carrier," ANNALES CHIRURGIAE ET GYNAECOLOGIAE (1993), pp. 77-84, vol. 207, University of Tampere, Finland, University of Helsinki, Finland.
\I/	GAO, TIE-JUN, *Bioactive Delivery System for Extracted Bone Morphogenetic Proteins* (1996), Acta Universitatis Tamperensis, ser

Examiner	Date		$\overline{}$
1 1			
Signature	I Considered	1	
AFMAARIAN A NI AM		<u> </u>	

Substitute for form 1-	49A/PTO &	1449B/PTO		Complete if Known		
		FIRST		Application Number	10/759,244	
INFO	RMAT	ON DIS	CLOSURE	Filing Date	January 20, 2004	
STAT	STATEMENT BY APPLICANT			First Named Inventor	Sam T. Lindholm et al.	
	(use as ma	ny sheets as n	ecessary)	Examiner Name		
Sheet	3	of	5	Attorney Docket Number	032469-007	

	NON-PATENT LITERATURE DOCUMENTS					
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					
	GERHART T.N. at al. "Healing Segmental Femoral Defects in Sheep Using Recombinant Human Bone Morphogenetic Protein." CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1993), pp. 317-326, no. 293, J.B. Lippincott Company, Philadelphia, PA.					
DR	HARRIS, E.L.V., "Concentration of the Extract", Chapter 3, In. Protein Purification Methods: A Practical Approach, Harris et al. (Eds.), September, 1989, IRL Press, Oxford, UK, page(s) 125-130.					
	HECKMAN, J.D., et al., "The Use of Bone Morphogenetic Protein in the Treatment of Non-Union in a Canine Model "THE JOURNAL OF BONE AND JOINT SURGERY (1991), pp. 750-764, vol. 73-A, The Journal of Bone and Joint Surgery, American Volume, Boston, MA.					
	HELM, G.A., et al. "I bilization of type I collegen gal, demineralized bone matrix, and bone morphogenatic protein-2 to enhance autologous one lumbar spinal fusion," J. NEUROSURGERY. (1997), pp. 93-100, vol. 86, Charlottesville, VA.					
	HOGAN, B.L.M., "Bone morphogenetic proteins: multifunctional regulators of vadebrate development," CENES & DEVELOR MENT (1995), pp. 1580-1594, vol. 10, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY.					
	HOLLIGER, E.H., et al., "Morphology of the Lumbar Intertransverse Process Fusion Mass in the Rabbit Model: A Comparison Between Two Bone Graft Materials — mbmP-2 and Autograft," Journal of Spinal Disorders (1996), pp. 125-128, vor. 9, Lippincott Williams & Wilkins, Hagerstown, MD.					
	HOLLINGER, J. & LEONG, K., "Poly(a-hydroxy acids): carriers for bone morphogenetic proteins." BIOMATERIALS (1996) op 187-194 vol. 17, Elsevier Science Limited, Butterworth-Heinemann, Oxford, England.					
	HOTZ, G. & HARR, G., "Bone substitute with osteoinductive biomaterials – current and future clinical applications," INT. J. ORAL MAXILLOFAC. SURG. (1994), pp. 413–417, vol. 23, Munksgaard, Copennagen, Denmark					
	HU, Y.Y., "Experimental studies on reconstituted xenograft and its clinical application," Chinese Journal of Surgery, Vol. 31, no. 12, pp. 709-713, Zhonghua yi xue hui, Wai ke xue hui, Beijing, China.					
	JOHNSON, E.E. & URIST, M.R., "Distal Metaphyseal Tibial Nonunions Associated with Significant Bowing Deformity and Cortical Some Loss: Treatment with Human Borne Morphogenetic Protein (n-BMP) and Internal Fixation." (1989), pp. 613-620, vol. 63, Nippon Seikeigeka Gakkal Zasshi, Japan.					
	JOHNSON, E.E., et al., "Repair of Segmental Defects of the Tibia with Cancellous Bone Grafts Augmented with Human Bone Morphogenetic Protein," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 249-257, ho. 236, JB Lippincoti, Philadelphia, PA.					
	JOHNSON F. F. et et. "Bone Morphogenetic Protein Augmentation Grafting of Resistant Femoral Nonunions," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 257-265, no. 230, JB Lippincott, Philadelphia, PA.					
	IOHNSON, E. E. et al. "Autogeneic Cancellous Bone Grafts in Extensive Segmental Ulnar Defects in Dogs." CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1989), pp. 254-265, no. 243, JB Lippincott, Philadelphia, PA.					
DR	JORTIK, LEENA, "Native Bone Morphogenetic Protein Purification and Action On Rat Skeletal Muscle Myoblast" (1998), Academic Dissertation Acta Universitatis Tamperensis 629, Tampere, Finland					
DR	JORTIKKA, LEENA, et al., "Partially Purified Reindeer (Rangifer Tarandus) Bone Morphogenetic Protein Has a High Bone-Forming Activity Compared With Some Other Artiodactyls," Clinical Orthopaedics and Related Research (1993), pp. 33-37, vol. 297, J. B. Lippincott Company					
DR	JORTIKKA et al., "Purification of monocomponent bovine bone morphogenetic protein in a water-soluble form", Annales Chirugiae et Gynacologiae, Supplementum, (1993) 207:25-30.					
	2380596, Nippon Seikeigeka Gakkai Zasshi, Japan.					
DR	KIRKER-HEAD, CARL A., et al., "Long-Term Healing of Bone Using Recombinant Human Bone Morphogenetic Protein 2," Clinical Orthopaedics and Related Research (1995), pp. 222-230, vol. 318, Lippincott-Raven Publishers					
	KUBOKI. Y. et al. "Two Distinctive BMP-Carriers Induce Zonal Chondrogenesis and Membranous Ossification. Respectively: Geometrical Factors of Matrices for Cell-Differentiation," CONNECTIVE TISSUE RESEARCH (1995), pp. 219-226, vol. 32, Taylor & Francis, Philadelphia, PA.					
	LEE. S.C. et al. "Healing of lame segmental defects in rat femure is alded by RhBMP-2 in PLGA matrix." JOURNAL OF BIOMEDICAL MATERIALS RESEARCH (1994), pp. 1149-1156, vol. 28, Wiley Interscience, Hoboken, NJ.					
	LINDE, A. and HEONER, E., *Recombinant Bone Morphogenetic Protein-2 Enhances Bone Healing, Guided by Osteopromotive e- PIFE Membranes: An Experimental Study in Rats,* CALCIFIED TISSUE INT. (1995), pp. 549-553, vol. 56, Springer-Verlag, NY.					
	I INDHOLM T.S. of al. "Response of Bone Marrow Strome Calls to Demogratized Codical Bone Matrix in Experimental Spinal Fusion in Rabbits," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 296-302, no. 230, JB Lippincott, Philadelphia, PA.					
	LINDHOLM, T.C., et al., "Bone Morphogenetic Proteins Regenerating Skull and Maxillo-Mandibular Defects." HONE MORPHOGENETIC					
DR	LINDHOLM, T.S. and GAO, T.J., 'Functional Carriers for Bone Morphogenetic Proteins,' Annales Chirurgiae et Gynaecologiae Supplementum, (1993), pp. 3-12, vol. 82, University of Helsinki, Helsinki, Finland.					
xaminer ignature	Date Considered					
	: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. 5 609. Draw line through citation if not in					

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

· Substitute for form	1449A/PTO & 1	449B/PTO		Complete if Known		
ł	Į	FIRST		Application Number	10/759,244	
INFO	RMATI	ON DI	SCLOSURE	Filing Date	January 20, 2004	
STAT	STATEMENT BY APPLICANT			First Named Inventor	Sam T. Lindholm et al.	
		ny sheets as	nocessery)	Examiner Name		
Sheet	4	of	5	Attorney Docket Number	032469-007	

	NON-PATENT LITERATURE DOCUMENTS
xaminer Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
DR	LINDHOLM, TOM C., "Calvarial Reconstruction With Implants Of: Hydroxyapatite, Autogenous Bone Marrow, Allogeneic Demineralized Bone Matrix and Bovine Bone Morphogenetic Protein," Dissertation, University of Tampere and University of Turku, Finland (1995), pp. 8-280, Lastupaino-Yhliöl Oy, Rauma, Finland
DR	LINDHOLM, T. SAM, M.D., Ph.D., "Tissue Engineering Intelligence Unit, Bone Morphogenetic Proteins: Biology, Biochemistry and Reconstructive Surgery" (1996), Chapters 3, 6, 12, 14, 15, 18, 19, R.G. Landes Company and Academic Press, Inc., Georgetown, Texas.
DR	LINDHOLM, T. S., et al., "Biological Activity of BMP to Type 1 and IV Collagen: A Preliminary Report," Department of Clinical Sciences, University of Tampere, pp. 45-50, Tampere, Finland.
	LOVELL, T.P., et al., "Augmentation of Spinal Fusion With Rope Morphogenetic Protein in Dego," Currient Orthopaches and Related Research (1989), pp. 266-274, no. 243, JB Lippincott, Philadelphia, PA.
DR	MARTTINEN, A., et al., "Protein in a Water-Soluble Form," New Trends וא Bone Grafting (1991), pp. 40-43, Acta Universitatis Tamperensis, ser B vol 40, Tampere, Finland.
	MIYAMOTO, S. & TAKAOKA, K., "Bone Induction and Bone Repair by Composites of Bone Morphogenetic Protein and Biodegradable Synthetic Polymers," ANNALES CHIRURGIAE EY GYNAECOLOGIAE Supplement. 69-76, vol. 82, University of Helsinki, Finland.
	MUSCHLER G.F. et al. *Evaluation of Human Bone Morphogenetic Brotein 2 in a Capino Spinel Fusion Medel, *Chinisht. ORTHOPAEDICS AND RELATED RESEARCH (1994), pp. 229-240, no. 308, J.B. Lippincott Company, Philadelphia, PA.
	NILSSON, O.S., et al., "Bone Repair Induced by Bone Morphogenetic Protein in Ulnar Defects in Dons." THE JOURNAL OF BONE AND JOINT SURGERY, British Volume, (1986), pp. 635-642, vol. 68-B, London, UK.
	ODA. S., at al., "Ectopic bane induction in recombinant human bane morphogenetic protein-2 (rhRMP-2) combined with biobasic calcium phosphate (BCP)." (1996), The Journal of Stomatological Society, Japan.
DR	OGAWA et al., "Bovine bone activin enhances bone morphogenetic protein-induced ectopic bone formation", J. Biol Chem. (1992 Jul 15) 267 (20) 14233-7.
	ONO 1. et al. *Promotion of the Osteogenatic Activity of Recombinant Human Bone Mombogenetic Protein by Prostaglandin F. * BONE (1996), pp. 581-588, vol. 19, Elsevier Science Inc., NY.
DR	PAJAMÄKI, K.J.J., et al., "Bone Matrix in Rat Abdominal Muscle Pouch," University of Tempere, Tampere; Abo Akademi University, Turku, University of Turku, Turku, Finland, pp. 132-138.
DR	PAJAMÄKI, K.J.J., et el., "Fibronectin and Collagen Types I and III in Aggressive Granulomatous Lesions Surrounding Hip Implants." University of Tampere, Tampere, Finland, pp. 300-304.
	PANGANIBAN, G.E.F., et al., *Biochemical Characterization of the <i>Drosophila dpp</i> Protein, a Member of the Transforming Growth Factor p Family of Growth Factors,* Molecular and Cellular Biology (1990), pp. 2669-2877, vol. 10, American Society for Microbiology, Washington, DC.
	PETIT, J.C. & RIPAMONTI, U., "Tissue Segregation Enhances Calvarial Osteogenesis in Adult Primates." THE JOURNAL OF CROMINDFACUL SURGERY (1994), pp. 34-43, vol. 5, Little, Brown & Co., Boston, MA.
-	RAGNI, P. & LINDHOLM T.S., "Interaction of Allogeneic Demineralized Bone Matrix and Porous Hydroxyapalite Bioceramics in Cumbar Interaction of Research (1991), pp. 292-299, no. 272, JB Lippincott, Philadelphia, PA.
	RAGNI, P., et et., "Spinel Fusion Induced by Persue Hydronyspetite Steeles (HA)," pp. 133-144, Helian Journal of Orthopsedies 8. Traumatology, Bologna, Italy.
	RAGNI, P.C. & LINDHOLM, T.S., *Bone Formation and Static Changes in the Thoracic Spine at Uni- or Rilateral Experimental Spondylodesis with Demineralized Bone Matrix (DBM),* pp. 237-252, Italian Journal of Orthopaedics & Traumatology, Bologna, Italy.
	RILEY F.H. at al. "Rons Mombogenstic Protein-2." CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1996), pp. 39-46, pp. 324, IR. Lippincott, Philadelphia, PA.
	SAILER, H.F. & KOLB, E., 'Application of purified bone morphogenetic protein (RMP) preparations in granic moville fesial ourgory.' JOURNAL OF CRANIO-MAXILLO-FACIAL SURGERY (1994), pp. 191-199, vol. 22, Churchill Livingstone, Edinburgh, Scotland.
	SAILER H.F. & KOLB. F., "Application of purified bone morphogenetic protein (BMP) in cranio-maxillo-facial surgery," Journal of Cranio-Maxillo-Facial Surgery (1994), pp. 2-11, vol. 22, Churchill Livingstone, Edinburgh, Scotland.
DR	SAMPATH, T.K. & REDDI, A.H., "Homology of bone-inductive proteins from human, monkey, bovine, and rat extracellular matrix," PROC. NATL. ACAD. Sci. USA (1983), pp. 6591-6595, vol. 80, National Academy of Sciences, Washington, DC.
- I	The state of the s

Examiner	Date
Signature	Considered
*EVALUATED. 1-10-12 - 1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-	

-Su: stitute for form 1	449A/PTO 8	1449B/PT	0	Complete if Known		
	[FIRS	T	Application Number	10/759,244	
INFO	RMATI	ON E	SCLOSURE	Filing Date	January 20, 2004	
STAT	STATEMENT BY APPLICANT			First Named Inventor	Sam T. Lindholm et al.	
	(use as mar	ny sheets	es necessary)	Examiner Name		
Sheet	5	of	5	Attorney Docket Number	032469-007	

	NON-PATENT LITERATURE DOCUMENTS
xaminer Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
DR	SAMPATH, T. KUBER, et al., "Bovine Osteogenic Protein is Composed of Dimers of OP-1 and BMP-2A, Two Members of the Transforming Growth Factor-B Superfamily," The Journal of Biological Chemistry (1990), pp. 13198-13205, vol. 265, No. 22, The American Society for Biochemistry and Molecular Biology, Inc.
	SANDHU, H.S., et al., "Evaluation of m8MP-2 With an OPLA Carrier in a Canine Posterolateral (Transverse Process) Spinal Fusion Model," SPINE (1995), pp. 2669-2683, vol. 20, Lippincolt-Raven Publishers.
	SANDHU, H.S., et al., "Effective Doses of Recombinant Human Bone Morphogenetic Protein-2 in Experimental Spinal Fusion." SPINE (1996), pp. 2115-2122, vol. 21, Lippincott Williams & Wilkins, Hagerstown, MD.
	SCHIMANDLE, J.H., et al., "Experimental Spinal Fusion With Recombinant Human Bone Morphogenetic Protein-2," SPINE (1995), pp. 1326-1337, vol. 20, Lippincott Williams & Wilkins, Hagerstown, MD.
	SHEEHAN. J.P. at al., "Molecular Methods of Enhancing Lumbar Spine Fusion," Neurosurgery (1996),pp. 548-554, vol. 39.
	STAEHLING-HAMPTON, K., et al., "Specificity of Bone Morphogenetic Protein-related Factors". Cell Fate and Gene Expression. Changes in <i>Drosophila</i> Embryos Induced by decapentaplegic but not 60A," CELL GROWTH & DIFFERENTIATION (1994), pp. 585-593, vol. 5, American Association for Cancer Research, Philadelphia, PA.
	SUN, Y., of ol., *Repair of large cranial defect using alloganeic cranial hope and hope morphogenetic protein * PubMed 7600438 (1995), Chinese Journal of Plastic Surgery and Burns, Beijing, China.
	TORIUMI, D.M., et al., "Mandibular Reconstruction With a Recombinant Bone-Inducing Factor." ARCH OTOLARYNGOL HEAD NECK SURG (1991), pp. 1101-1112, vol. 117, American Medical Association, Chicago, IL.
	URIST, M.R., et al., "Regeneration of an enchondroma defect under the influence of an implant of human bone morphogenetic protein," THE JOURNAL OF HAND SURGERY (1986), pp. 417-419, Vol. 11A, Churchill Livingstone, Secaucus, NJ.
DR	URIST, M. R., et al., "Native Bone Morphogenetic Protein," University of Tampere Editorial Board (1992), pp. 27-39, Tampere, Finland.
DR	URIST, M. R., et al., "Purification of bovine bone morphogenetic protein by hydroxyapatite chromatography," Proc. Natl. Acad. Sci. USA (1984), pp. 371-375, vol. 81.
DR	URIST, MARSHALL R., "The search for and the discovery of bone morphogenetic protein (BMP)," Bone Grafts, Derivatives and Substitutes (1994), Chapter 17, pp. 315-362, Butterworth-Heinemann Ltd., Jordan Hill, Oxford, U.K.
	VAN EEDEN, S.P. & RIPAMONTI, U., 'Bone Differentiation in Porous Hydroxyapatite in Baboons Is Regulated by the Geometry of the Bobstratom: implications for Reconstructive Cramonacian Surgery,' PLASTIC AND RECONSTRUCTIVE SURGERY (1994), pp. 959-966, vol. 93, Lippincott Williams & Wilkins, Hagerstown, MD.
DR	VILJANEN, V.V., et el., "Partial Purification and Characterization of Bone Morphogenetic Protein from Bone Matrix of the Premature Moose (Alces alces): Degradation of Bone-Inducing Activity during Storage," (1996), pp. 447-460, vol. 28, European Surgical Research, Karger, Basel, Switzerland.
	VILJANEN, V.V., "Allogeneic and xenogeneic bone morphogenetic protein in skeletal reconstruction," (Academic Dissertation)
DR	VILJANEN, V. V., et al., "Xenogeneic moose (Alces alces) bone morphogenetic protein (mBMP)-Induced repair of critical-size skull defects in sheep," International Journal of Oral Maxillofacial Surgery (1996), pp. 217-222, vol. 25, University of Tampere, Tampere and University of Helsinki, Helsinki, Finland.
DR	VILJANEN, V. V., et al., "List of References On Demineralized Bone Matrix Induced Osteogenesis and Research of Bone Morphogenetic Proteins During the Period From 1951 Through 1995," Tissue Engineering Intelligence Unit, Bone Morphogenetic Proteins: Biology, Biochemistry and Reconstructive Surgery (1996), Appendix pp. 242-308, R. G. Land
	WHARTON, K.A. at al. *Drosophila 60A gene, another transforming growth factor & family member, is closely related to human bone morphogenetic proteins,* PROC. NATL. ACAD. Sci. USA (1991), pp.9214-9218, vol. 88, National Academy of Sciences, Washington, DC.
	WOLEE MW & COOK S.D. "Use of estecinductive implents in the treatment of bone defects." Mission Processes
	YASKO, A.W. et al., The Healing of Segmental Bone Defects, Induced by Recombinant Human Bone Morphogenetic Protein (INBMP-2). The Journal of Bone and Joint Surgery, (1992), pp. 639-670, vol. 74-A, American Ed. Journal of Bone and Joint Surgery, Boston, MA.

	······································		
Examiner	1- 1 1 14-14-14-1	Date	
Cinneture	/David Romeo/ (10/01/2006)	90.0	1
Signature	/ David Romeo/ (10/01/2000)	Considered	l i
*EYAMINED: 1	altial if and an area area ideard whether are at 1949 at 1		<u> </u>



10=32469-000007

United States Patent and Trademark Office UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov DEC 19 2006 OTICE OF ALLO FEE(S) DUE EXAMINER 21839 7590 10/03/2006 ROMEO, DAVID S **BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404** ART UNIT PAPER NUMBER **ALEXANDRIA, VA 22313-1404** 1647 DATE MAILED: 10/03/2006 APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/759,244 01/20/2004 Sam T. Lindholm 032469-007 7086

TITLE OF INVENTION: OSTEOGENIC DEVICE AND A METHOD FOR PREPARING THE DEVICE

APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional YES \$700 \$300 \$0 \$1000 01/03/2007

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.____

PART B - FEE(S) TRANSMITTAL

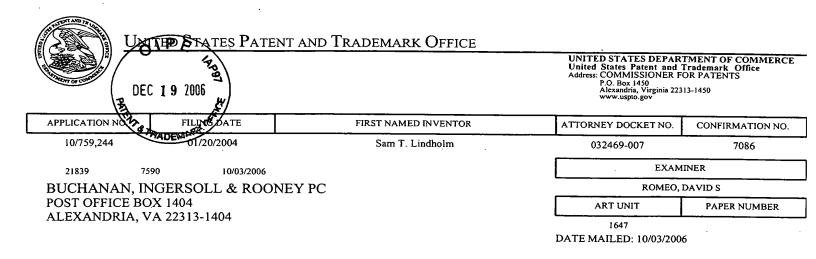
Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

			or <u>Fax</u>	(57)	()-273-2885	14 LLJ	13-1430		
NSTRUCTIONS: This ppropriate. All further indicated unless corrected in the indicated unless corrected in a contract of the indicated unless corrected in the indicated in the i	form should be used f correspondence includir ed below or directed oth tions.	or transmitting the ISSU on the Patent, advance of the Patent, advance of the Patent, by (a	JE FEE and PUBLIC rders and notification a) specifying a new c	of m	ON FEE (if require aintenance fees will condence address; a	d). Blo l be ma nd/or (b	cks 1 through 5 shilled to the current of indicating a separ	ould be completed where correspondence address a ate "FEE ADDRESS" fo	
21839 BUCHANAN, POST OFFICE I	7590 10/03 INGERSOLL & I	ROONEY PC	OIPE	Fee(s paper have	s) Transmittal. This is is. Each additional pits own certificate of Certificate.	certifica paper, su f mailin	ate cannot be used for uch as an assignment of transmission. Mailing or Transmission.	domestic mailings of the rany other accompanying to r formal drawing, must also deposited with the United class mail in an envelope bove, or being facsimile te indicated below.	
	-	THE STATE OF THE S						(Depositor's name)	
		· AN	MARMARIA					(Signature)	
				느				(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVEN	TOR		TTORN	EY DOCKET NO.	CONFIRMATION NO.	
10/759,244 TITLE OF INVENTION	01/20/2004 I: OSTEOGENIC DEVIC	CE AND A METHOD FO	Sam T. Lindholm OR PREPARING THE		VICE	03	32469-007	7086	
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSUE F	FEE	TOTAL FEE(S) DUE	DATE DUE	
nonprovisional	YES	\$700	\$300		\$0	<u> </u>	\$1000	01/03/2007	
EXAM	IINER	ART UNIT	CLASS-SUBCLASS	;]					
ROMEO,	DAVID S	1647	530-417000						
. Change of correspondence address or indication of "Fee Address" (37 IFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			(1) the names of a or agents OR, alter (2) the name of a registered attorney 2 registered patent	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.					
PLEASE NOTE: Unitecordation as set fort (A) NAME OF ASSIG	less an assignee is ident h in 37 CFR 3.11. Comp GNEE		data will appear on t T a substitute for filin (B) RESIDENCE: (C	he pa g an a	tent. If an assignee ssignment. and STATE OR CO	UNTRY	7)	cument has been filed for	
Please check the appropr	riate assignee category or	categories (will not be pr	rinted on the patent):	<u> </u>	Individual	oration	or other private grou	p entity Government	
Ala. The following fee(s) are submitted: Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies			 b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) A check is enclosed. Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form). 						
a. Applicant claim	tus (from status indicate as SMALL ENTITY state	us. See 37 CFR 1.27.	☐ b. Applicant is no						
NOTE: The Issue Fee an nterest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be accepte ates Patent and Trademark	d from anyone other the Office.	nan th	e applicant; a registe	ered atto	orney or agent; or the	assignee or other party in	
Authorized Signature					Date				
Typed or printed name			Registration No.						
This collection of inform	nation is required by 37 (CFR 1.311. The information	on is required to obtain	or re				by the USPTO to process)	

an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 562 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 562 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

A	application No.	Applicant(s)
1	0/759,244	LINDHOLM ET AL.
Notice of Allowability	xaminer	Art Unit
19 2006 👊	Pavid S. Romeo	1647
The MAILING DATE of this communication appears being allowable, PROSECUTION ON THE MERITS IS (O erewith (or previously mailed), a Notice of Allowance (PTOL-85) or OTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHT the Office or upon petition by the applicant. See 37 CFR 1.313 are. This communication is responsive to 01/20/2004.	R REMAINS) CLOSED in other appropriate community. This application is s	this application. If not included unication will be mailed in due course. T
. ⊠ The allowed claim(s) is/are <u>16 and 17</u> .		
Acknowledgment is made of a claim for foreign priority under a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have be	een received.	
2. Certified copies of the priority documents have be		
 Copies of the certified copies of the priority docur International Bureau (PCT Rule 17.2(a)). 	nents have been received	In this national stage application from
* Certified copies not received:		
Applicant has THREE MONTHS FROM THE "MAILING DATE" of noted below. Failure to timely comply will result in ABANDONMEN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	this communication to file NT of this application.	a reply complying with the requiremen
. A SUBSTITUTE OATH OR DECLARATION must be submitte INFORMAL PATENT APPLICATION (PTO-152) which gives it		
. ☐ CORRECTED DRAWINGS (as "replacement sheets") must b (a) ☐ including changes required by the Notice of Draftsperson 1) ☐ hereto or 2) ☐ to Paper No./Mail Date		ı (PTO-948) attached
(b) ☐ including changes required by the attached Examiner's A Paper No./Mail Date	mendment / Comment or	in the Office action of
Identifying indicia such as the application number (see 37 CFR 1.84 each sheet. Replacement sheet(s) should be labeled as such in the	(c)) should be written on the header according to 37 CF	ne drawings in the front (not the back) of R 1.121(d).
 DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT FO 	OF BIOLOGICAL MATE OR THE DEPOSIT OF BIO	ERIAL must be submitted. Note the DLOGICAL MATERIAL.
ttachment(s)	E Filmer - co	Formal Date at Assalination
. ☐ Notice of References Cited (PTO-892) . ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)		formal Patent Application
. ☐ Notice of Drantperson's Patent Drawing Review (P10-948) . ☐ Information Disclosure Statements (PTO/SB/08),	Paper No./	ummary (PTO-413), Mail Date Amendment/Comment
Paper No./Mail Date <u>0804</u> Examiner's Comment Regarding Requirement for Deposit	<u> </u>	Statement of Reasons for Allowance
of Biological Material	9. ⊠ Other See 0	Continuation Sheet.
		Daniel Rome
		David S Romeo Primary Examiner Art Unit: 1647

Continuation Sheet (PTOL-37)

Application No. 10/759,244

Continuation of Attachment(s) 9. Other: The information disclosure statement filed 08/02/2004 fails to fully comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The non-complying information not being considered. It is acknowledged that applicants indicate that the listed references were made of record in parent U. S. Application No. 09/125,963. However, inspection of the parent applications has revealed that the indicated non-complying references are not of record in the parent application. Copies of the non-complying references have not been provided.